

Welcome to SPL Update and Downstream Use





Structured Product Labeling

Definition of SPL

- SPL = Structured Product Labeling
- XML Format (eXtensible Markup Language)
 - Textual Content Displayed, Metadata Hidden
- Comprised of 3 Elements
 - Facility Elements (Registration/Listing)
 - Product Elements (Data Elements)
 - Labeling Elements (Content of Labeling {CoL})



SPL History

2003

- (Dec) Published Final Rule: Electronic Labeling Rule

2004

- (Jun) Electronic Labeling Rule Effective (NDA, ANDA, BLA)

2005

- (Apr) Guidance: Providing Regulatory Submissions in Electronic Format – CoL
- (Oct) SPL is CDER Requirement

2007

- FDAAA: Electronic Registration and Listing Codified (eDRL)

2008

- (Jun) Guidance: Indexing Structured Product Labeling
- (Oct) – SPL is CBER Requirement

2009

- (Jun) SPL Requirement for OTC products & CVM
- (Jun) Electronic Registration & Drug Listing Mandatory

DailyMed – Drug Listing

RAPAFLO[®]
sildenafil capsules

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RAPAFLO[®] safely and effectively. See full prescribing information for RAPAFLO[®] (sildenafil) capsules for oral use.
Initial U.S. Approval: 2005

INDICATIONS AND USAGE
RAPAFLO[®] is an alpha-1 adrenergic receptor antagonist, is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). (1)
RAPAFLO[®] is not indicated for the treatment of hypertension.

US DOSAGE AND ADMINISTRATION
• If any capsules taken only once daily with a meal. (2.1)
• If any capsules taken only once daily with a meal for those with moderate renal impairment. (See Renal Impairment, Hypertension, and Hypotension) (2.2)

ADVERSE REACTIONS
See full prescribing information for RAPAFLO[®] (sildenafil) capsules for oral use.

CONTRAINDICATIONS
• Patients with severe renal impairment (CrCl < 30 mL/min). (4)
• Patients with severe hepatic impairment (Child-Pugh score > 3). (4)
• Concomitant administration with strong CYP3A4 and CYP2C9 inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, fluconazole). (4)

WARNINGS AND PRECAUTIONS
• Patients hypersensitive with or without symptoms (e.g., dizziness, may develop when beginning RAPAFLO[®] treatment). (5.1)
• In patients with moderate renal impairment, RAPAFLO[®] should be initiated at 5 mg once daily. (5.2)
• RAPAFLO[®] should not be used in combination with other alpha-blockers. (5.3)
• Caution should be taken to avoid orthostatic hypotension when RAPAFLO[®] is used in the treatment of patients with BPH. (5.4)
• Instruct patients to avoid grapefruit juice while taking RAPAFLO[®] because of the possibility of increased plasma drug levels. (5.5)

ADVERSE REACTIONS
Most common adverse reactions (incidence ≥ 2%) are: dyspepsia, dizziness, headache, rhinitis, back pain, and nasal congestion. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Watson Pharmaceuticals, Inc. at 1-800-274-6629 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
• Strong CYP3A4 inhibitors (e.g., ketoconazole) can increase plasma concentrations of RAPAFLO[®]. Concomitant use is not recommended. (7.2)
• Adverse reaction interactions involving cytochrome P450 have not been determined. However, interactions are expected and recommended use is not recommended. (7.3)

USE IN SPECIFIC POPULATIONS
• Renal impairment: Sildenafil plasma levels are increased in patients with renal impairment. (8)
• Hepatic impairment: Concomitant use is not recommended. (8)

See full prescribing information for RAPAFLO[®] (sildenafil) capsules for oral use.

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See full prescribing information for RAPAFLO[®] (sildenafil) capsules for oral use.

DailyMed About DailyMed - Windows Internet Explorer

http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=12992

Search: []

Units: [] Drug Name [] NDC Code [] Drug Class []

RAPAFLO[®] (sildenafil) capsule
[Watson Pharma, Inc.]

RxNorm Names
[Buyer Refill Request Form]

Category	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		New Drug Application

Drug Label Sections

Description Clinical Pharmacology Indications & Usage Contraindications Warnings Precautions
Adverse Reactions Overdose Dosage & Administration How Supplied Patient Counseling Information
Supplemental Product Material Related Warnings Patient Package Insert Highlights Full Table of Contents
Medication Guide

HIGHLIGHTS OF PRESCRIBING INFORMATION
RAPAFLO[®] (sildenafil) capsules
Revised: November 2008
Rx only
17576121109

These highlights do not include all the information needed to use RAPAFLO[®] safely and effectively. See full prescribing information for RAPAFLO[®] (sildenafil) capsules for oral use.
Initial U.S. Approval: 2005

RECENT MAJOR CHANGES
WARNINGS AND PRECAUTIONS, Pharmacodynamic Drug-Drug Interactions (5.5): 11/2008

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Paper Package Insert
to
Electronic Format →

Definition & History

DailyMed a handy site!



The image shows a screenshot of the DailyMed website interface. At the top, there is a red header with the 'Daily Med' logo and the text 'Current Medication Information'. Below the header is a search bar with a 'GO' button. To the right of the search bar are radio buttons for 'Limits: Drug Name', 'NDC Code', and 'Drug Class'. The search results show 'RAPAFLO (silodosin) capsule [Watson Pharma, Inc.]'. To the right of the search results is a red box labeled 'RxNorm Names' with a link to 'Review RxNorm Normal Forms'. Below the search results is a table with three columns: 'Category', 'DEA Schedule', and 'Marketing Status'. The 'Category' column contains 'HUMAN PRESCRIPTION DRUG LABEL', the 'DEA Schedule' column is empty, and the 'Marketing Status' column contains 'New Drug Application'. Below the table is a section titled 'Drug Label Sections' with a grid of buttons for various sections: Description, Clinical Pharmacology, Indications & Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Overdosage, Dosage & Administration, How Supplied, Patient Counseling Information, Supplemental Patient Material, Boxed Warning, Patient Package Insert, Highlights, Full Table of Contents, and Medication Guide. Below the 'Drug Label Sections' is a section titled 'HIGHLIGHTS OF PRESCRIBING INFORMATION' which includes the drug name 'RAPAFLO® (silodosin) capsules', the revision date 'Revised: November 2009', the text 'Rx only', the NDC number '17376121109', and a statement that the highlights do not include all the information needed to use the drug safely and effectively. Below this is a section titled 'RECENT MAJOR CHANGES' which includes the text 'WARNINGS AND PRECAUTIONS, Pharmacodynamic Drug-Drug Interactions (5.5) 11/2009'. Below this is a section titled 'INDICATIONS AND USAGE' which includes the text 'RAPAFLO, an alpha-1 adrenergic receptor antagonist, is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). (1) RAPAFLO is not indicated for the treatment of hypertension.' Below this is a section titled 'DOSAGE AND ADMINISTRATION'.

Daily Med
Current Medication Information

Search : **GO**

Limits: ☐ Drug Name ☐ NDC Code ☐ Drug Class

RAPAFLO (silodosin) capsule
[Watson Pharma, Inc.]

RxNorm Names
[Review RxNorm Normal Forms](#)

Category	DEA Schedule	Marketing Status
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Medication Guide

HIGHLIGHTS OF PRESCRIBING INFORMATION

RAPAFLO® (silodosin) capsules
Revised: November 2009
Rx only

17376121109

These highlights do not include all the information needed to use RAPAFLO® safely and effectively. See full prescribing information for RAPAFLO.

RAPAFLO® (silodosin) capsule for oral use
Initial U.S. Approval: 2008

RECENT MAJOR CHANGES

WARNINGS AND PRECAUTIONS, Pharmacodynamic Drug-Drug Interactions (5.5) 11/2009

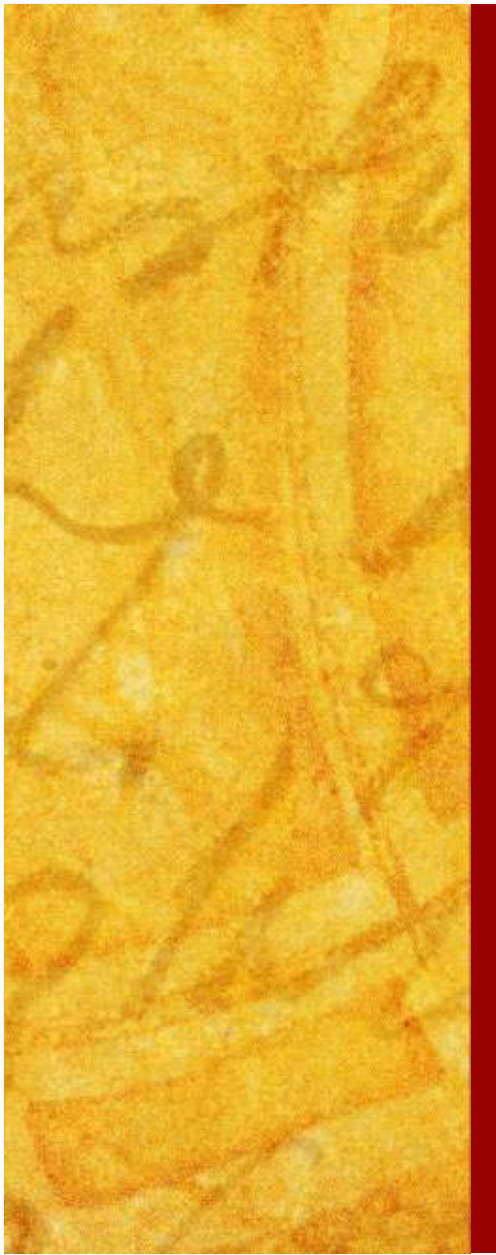
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DOSAGE AND ADMINISTRATION

Definition & History





OMG we spent a
fortune on Drug
Listing – What is
next?????

Glad you asked that
question...



Possibilities

Possibilities of Downstream uses

- SPL Metadata Not Only Content of Labeling
- Data Potential Only Beginning to be Realized
 - 2008 – FDA “Indexes” SPL Upon Submission

Possibilities



Possibilities of Downstream uses

- SPL Metadata Not Only Content of Labeling
- Data Potential Only Beginning to be Realized
 - 2008 – FDA “Indexes” SPL Upon Submission

Indexing refers to the insertion of machine-readable tags, which do not appear in actual printed labeling, that enable users with clinical decision support tools and electronic prescribing systems to rapidly search and sort product information.

Possibilities



Possibilities of Downstream uses

- SPL Metadata Not Only Content of Labeling
- Data Potential Only Beginning to be Realized
 - 2008 – FDA “Indexes” SPL Upon Submission
 - 2010 – Search by NDC Number
 - 2011 – Pharmacologic Class Indexing
 - 2011 – DailyMed Mobile App

Possibilities



SPL Update and Downstream uses of SPL

- Keep Labeling up to date on SPL!
- What else can SPL be used for? (Public safety & Quantifiable cost savings)
- Return of Investments
- SPL Use inside the Pharmaceutical Industry
- Value of Permanent Link – Use on websites
- SPL on Hand-Held Devices
- Consumer Use of SPL!
- Etc.

Possibilities of Downstream uses

- Patient Scan Bar Code and Read Labeling POS



Possibilities



Possibilities of Downstream uses

- Patients can search for products on the Internet



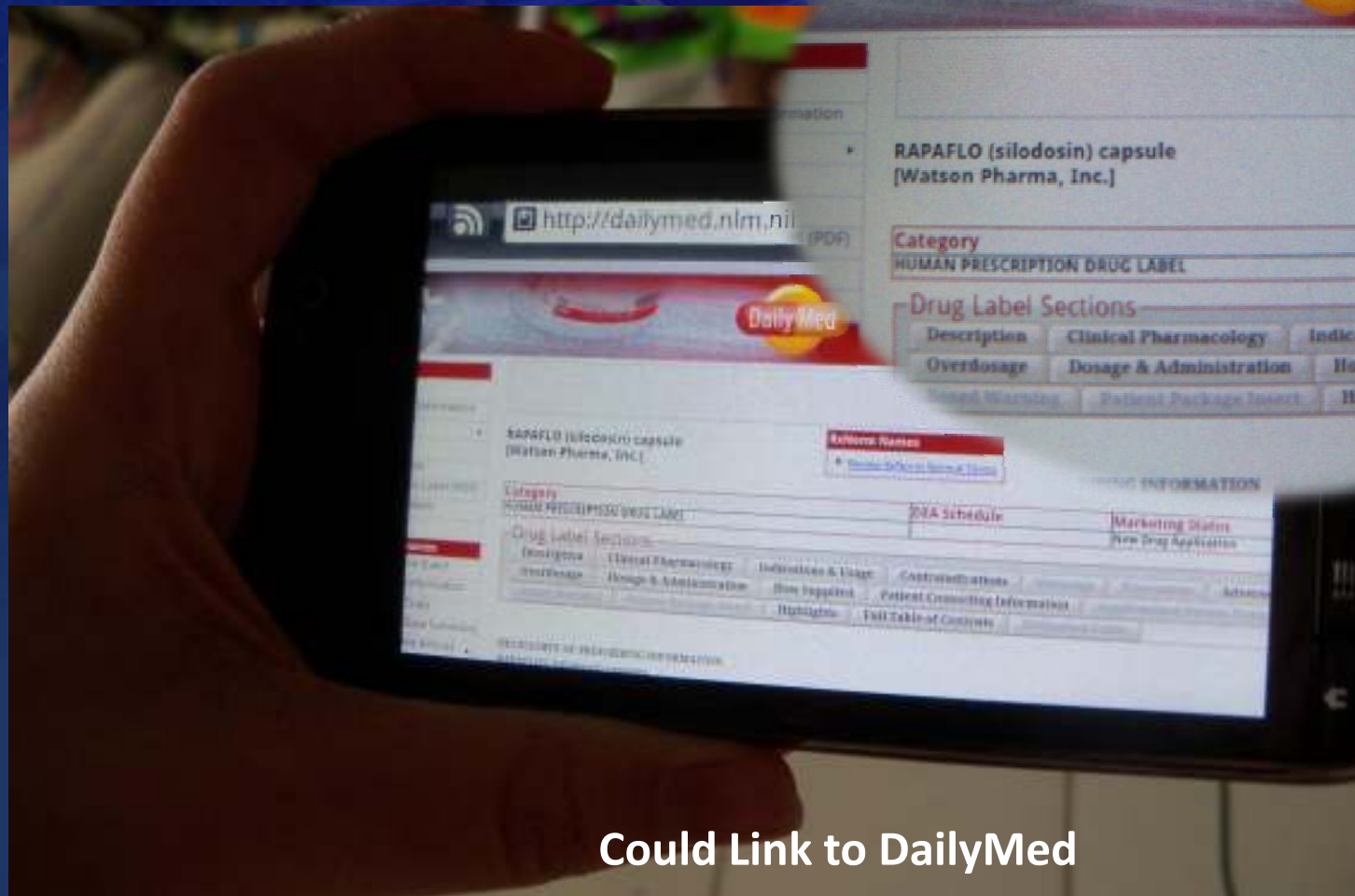
Currently Links to Retail Information

Possibilities



Possibilities of Downstream uses

- Patient Scan Bar Code and Read Label



Could Link to DailyMed

Possibilities



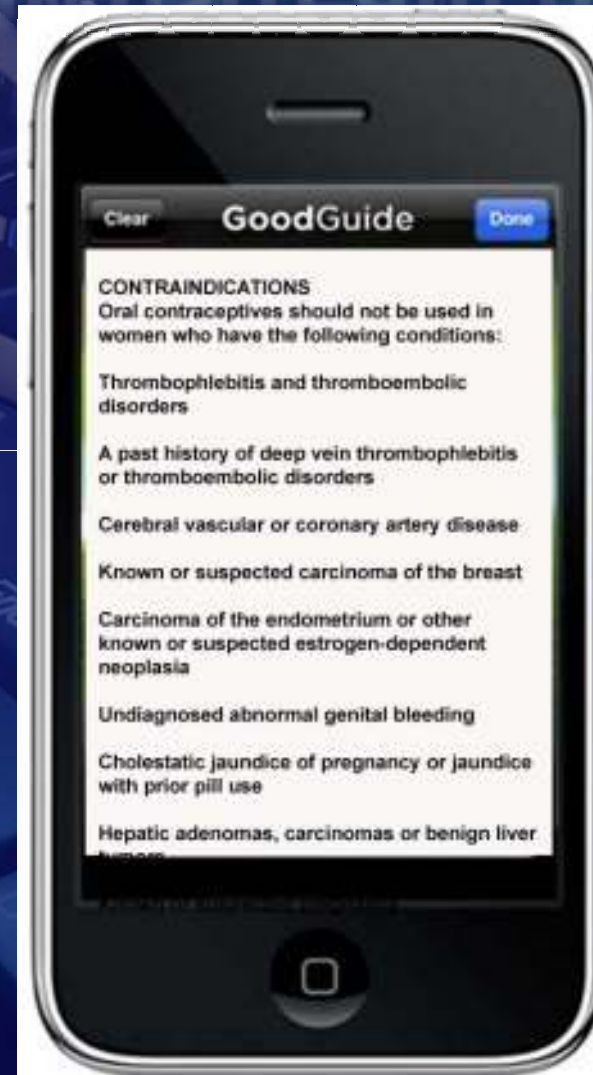
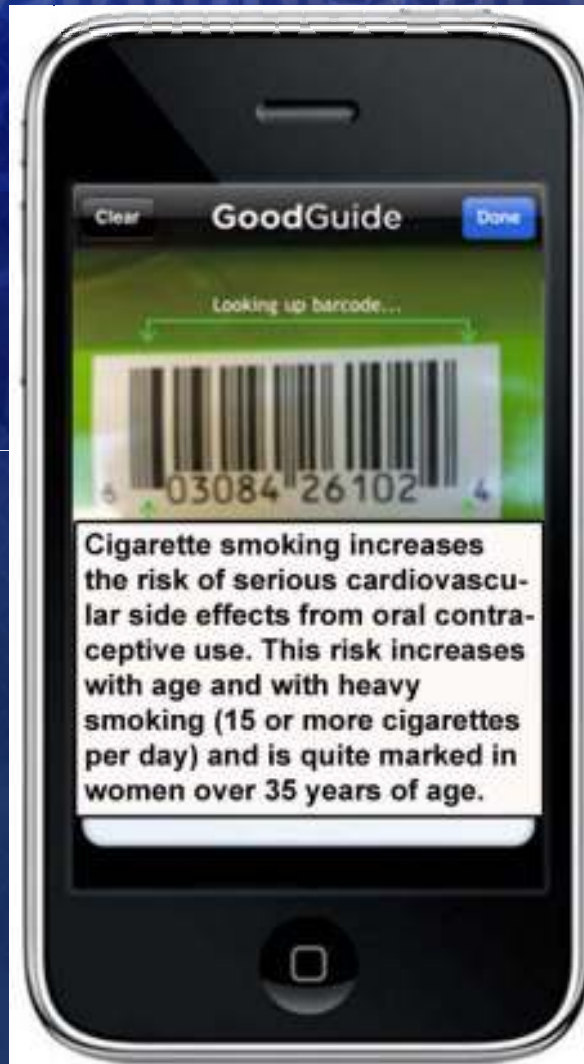
Possibilities of Downstream uses

- Patient Scan Bar Code and Read Labeling POS
 - Better Information Access Increases Self-Care
 - More Informed Patient Empowers H.C. Profes.
- SPL Data Linked to Health Information
 - Know Immediately Drug-Drug Interactions
 - Comparison/Aggregate Listing Warnings, Precautions, Contraindications, Side Effects
 - Immediate Cross-check to Dispensing Pharmacist
 - Give H.C. Professional Better Information Control

Possibilities



Possibilities of Downstream uses



Possibilities



Possibilities of Downstream uses

- SPL's XML Format Can Be Leveraged
 - Customized Style Sheets Can Be Used
 - "One XML Fits All"
 - Style Sheet Can:
 - Reorganize Information
 - Change Fonts and Viewing Size/Appearance
 - Display Only Selected Pieces of Information
 - Made to Fit Patient and Sponsor Needs

Possibilities



Testimonials



University of MD pharmacist interns Rachel and Kevin show their support for DailyMed on the iPhone. (Kevin likes it better than the paper insert he is holding.)



Pharmacy Technician Dan just learned how to access DailyMed on his iPhone!





Hello, my name is Priscilla and I am 75 years young. My husband recently visited his doctor and was prescribed some medication we thought was for pain and should be taken as needed. When a friend of mine pulled up DailyMed on her iPhone and told me they were indicated for Hypertension we called the doctor and he verified that he should be taking them every day. I rely on DailyMed along with my doctor to keep track of our medications now and feel much safer.



Hi, I'm Patricia. I have a large family with many children and pets so when someone gets sick I'm on charge of keeping track of what they take. I pull up Medication Guides on my iPhone while on the go! I showed a friend how to use the App and she realized that the medication her son was taking could be causing some new issues that he recently developed. She discussed it with her doctor, they changed medications and he no longer has these issues!

Dr. Don E Millner DDS and his office Manager Vena Wilson



Dr. Don E Millner DDS

PC FAGD FICOI

Dr. Don E. Millner is a nationally recognized cosmetic dentist with a fulltime private practice in Yardley, Pennsylvania. He has been voted "Best of Bucks" in 2005, 2006 and 2009 and has been featured in the New York Times, Philadelphia Inquirer and on Network TV. He received his doctorate from Temple University and his commitment to advanced studies has earned him a Fellowship in The Academy of General Dentistry.

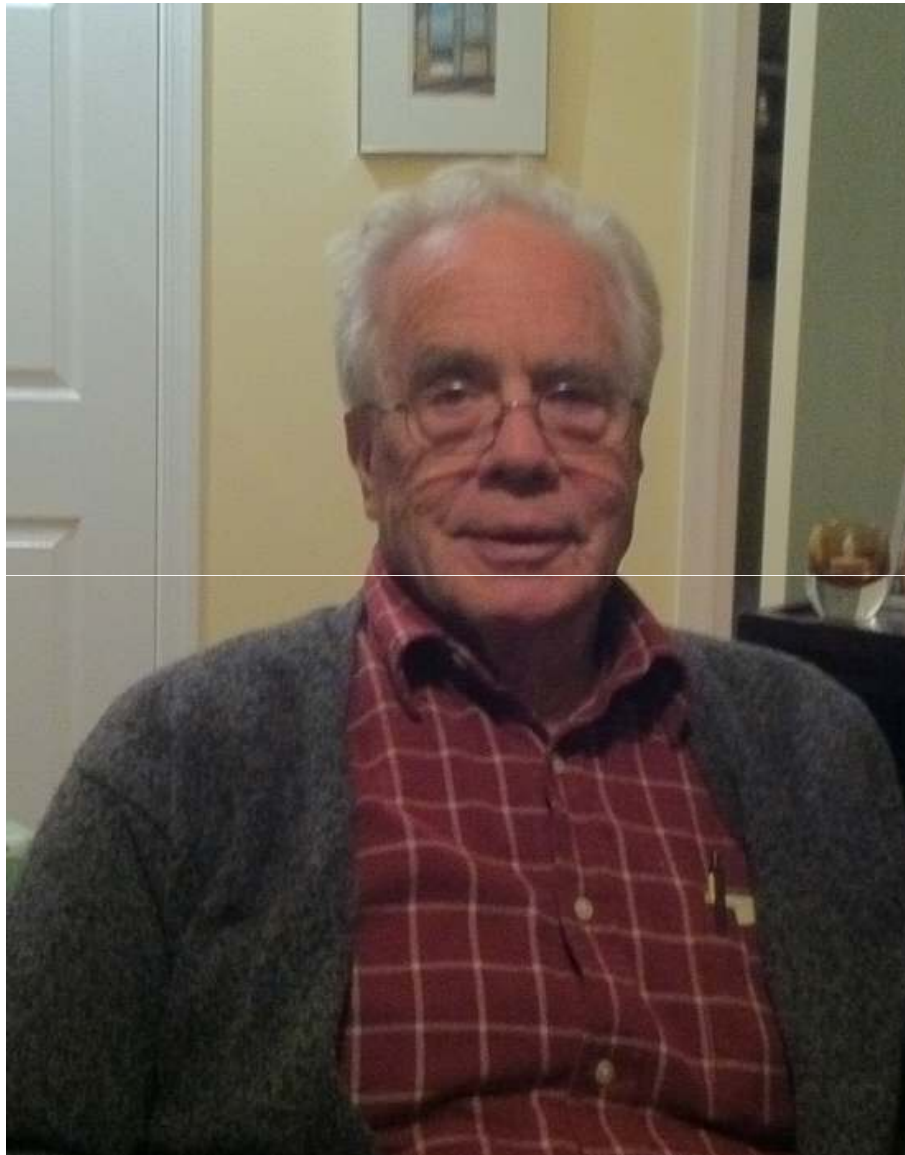
"My Office Manager, Vena Wilson uses DailyMed on a regular basis. We don't prescribe many medications, but like to always have current package inserts and/or medication guides on hand for patient safety. This is an extremely valuable website."

Rafal Czapla, PharmD



I wanted to say thank you for making me aware of the DailyMed App ! I have been using the full, desktop version of the website for several years, but I was not aware of the mobile app until our conversation. It is such a great tool, and the fact that I am able to use it whenever I please and wherever I am is priceless. As a pharmacist, my job does not end when I leave the pharmacy. I constantly have family members and friends asking me questions about the medication they're on or that they have seen on TV. Having access to a tool such as the DailyMed app, and not being tied to a desktop computer is a great help





Charles Montgomery, MD, retired physician, was looking for a PDR to have on hand in his office. A member of his family is involved with the downstream uses of SPL and showed him how to use DailyMed and pull up Pls, MedGuides and other labeling that is current and easy to use. When Dr. Montgomery returned home he made DailyMed a “Favorite” on his computer and consults it on a regular basis.

Thank you! Questions?

